Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13370

0 - FRONT

[redacted]

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER: DET-0833 13370

2. DATE OF COMPLAINT (Month/Day/Year): 02/22/99

3. FORM OF COMPLAINT
(1) [X] TELEPHONE
(2) [ ] LETTER
(3) [ ] VISIT

4. SOURCE OF COMPLAINT
(1) [X] CONSUMER
(2) [ ] GOVERNMENT
(3) [ ] TRADE SOURCE
(4) [ ] OTHER
[ ] L [ ] S [ ] F
(Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include ZIP Code): [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME [redacted]
WORK ( )

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT/INJURY
Complainant's brother (19 yrs. old) purchased "Metacuts" by Metaform, a dietary supplement purchased at [redacted] for energy during exercise. Complainant took four capsules (recommended dosage) daily off and on for three months. Complainant's brother became ill - not sleeping, agitated, shortness of breath, rapid heart rate, hallucinations.

See remarks....

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) [ ] NO (2) [X] YES
(Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) [ ] NO
(2) [X] YES
(If "yes" complete items a through d)

a. EIB (HFC-161) NOTIFIED
(1) [ ] NO
(2) [X] YES
DATE 02/18/99

b. TYPE SYMPTOMS — ONSET (HR.)
1. [ ] VOMITING
2. [ ] NAUSEA
3. [ ] DIARRHEA
4. [ ] FEVER
5. [ ] SKIN/EYE IRR.
6. [X] HEADACHE 3 hrs
7. [X] OTHER See Above

c. ATTENDING HEALTH PROFESSIONAL
(1) [ ] NO (2) [X] YES
(If "yes" give name, address, and phone number) [redacted]

d. HOSPITALIZATION REQUIRED
(1) [ ] NO (2) [X] YES
(If "yes" give name, address, phone number and dates) [redacted]

FEB 1999
RECEIVED
DOMESTIC PROGRAMS BRANCH
CONSUMER COMPLAINT COORD.

8. PRODUCT AND LABELING
a. BRAND NAME: Metacuts
b. PRODUCT NAME: Metaform
c. SIZE AND PACKAGE TYPE: 60 capsule glass bottle
d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]
e. PACKAGE CODE/SERIAL NUMBER/ETC.: WN2658A
EXP/USE BY DATE: 09/30/01
f. DATE PURCHASED: 11/01/98
g. PRODUCT USED (If "yes" enter date) (1) [ ] NO (2) [X] YES
h. AMT REMAINING: 10 caps

9. MANUFACTURER/ DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: LOS-DO
b. C.F. NO.: NOCF
c. NAME AND LOCATION OF FIRM (Include ZIP Code)
Metaform
22647 Ventura Blvd.
Woodland Hills, California 91346
d. IMPORT PRODUCT
(1) [X] NO
(2) [ ] YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEYWORD
(1) CODE: RX
(2) DESCRIPTION: REACTION

b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [ ] OBLIGATION, NO VIOLATION
(3) [X] FDA ACTION INDICATED
(4) [ ] INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c. DISPOSITION
(1) [ ] IMMEDIATE FOLLOW-UP
(2) [ ] F/U NEXT EI
(3) [ ] CLOSED WITHOUT FURTHER INVESTIGATION
(4) [ ] REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) [ ] REFERRED TO STATE/LOCAL AGENCY (Closes file)
(6) [X] REFERRED TO OTHER FDA LOS DISTRICT
(7) [ ] REFERRED TO OC

11. PRODUCT CODE: 54YEY99

12. INFORMATION COPIES TO:
[ ] HFB-100 [ ] HFZ-343
[ ] HFD-730 [ ] HFC-181
[ ] HFV-236 [X] HFS-636

REMARKS
Ultimately the diagnosis by physician was that complainant's brother was borderline manic depressive and this aggravated the condition and brother was hospitalized 2/3-10/99. Complainant spoke to manufacturer and mfr does not believe episode is related to Metacuts.

Please note attached info I obtained via Internet: Ingredients include Ma Huang and ephedrine isomers etc. Mailed MedWatch form to complainant. Notified [redacted] also sent copy to CFSAN HFS-636. VIA FAX 1-22-99 - 4:10pm.

NAME AND TITLE
Linda R. Smith, Paralegal Specialist, DET-DO

DATE: 02/22/99

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FORM FDA 2516 (6/94)

[redacted]

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER: DET-0833

2.a. ACTION REQUESTED
- (1) ☐ INVESTIGATION
- (2) ☐ COLLECT SAMPLE
- (3) ☐ INSPECTION
- (4) ☐ OTHER:

2.b. REMARKS (Additional details) F/u to serious adverse reaction from individual taking food supplement containing Ephedrine. Obtain labeling; medical records from complainant to show any pre-existing medical conditions and medical records relating to adverse event. Collect samples of implicated product

2.c. REQUESTING OFFICIAL'S NAME AND TITLE: Sally S Eberhard Food Tech w-leader

2.d. DATE REQUESTED:

2.e. PRODUCT NAME: Metaform "Metatak"

3.a. ASSIGNED TO: Anthony R. Petriella Investigator

3.b. DUE BY: 4/02/99

4.a. ACTION TAKEN
- (1) ☒ INVESTIGATION
- (2) ☐ SAMPLE COLLECTED
- (3) ☐ INSPECTION
- (4) ☐ NONE

4.b. SAMPLE NUMBER(s): 32555

4.c. DESCRIPTION OF ACTION TAKEN

See continuation sheet for details

JUL 1999 RECEIVED DOMESTIC PROGRAMS BRANCH CONSUMER COMPLAINT COORD.

4.d. ACTION OFFICIAL'S NAME AND TITLE: Anthony R Petriella, Investigator

4.e. ACTION DISTRICT: Det

4.f. DATE COMPLETED: 3/30/99

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

5.a. HOME DIST.: DEN-DO

5.b. CF NO.: 172240

5.c. NAME AND ADDRESS: Weider Nutrition International 2002 South 5070 West S Salt Lake City UT 84104 (USA)

6. PROGRAM DATA

6.a. OPERATION	6.b. PAC	6.c. PRODUCT CODE
13	21R801	54YEY99

6.d EMP. HOME DIST.	6.e. EMP. NO.	6.f. POS CL.	6.g. HOURS
9	535	2	

7. EVALUATION
- (0) ☐ PENDING
- (1) ☐ NO ACTION INDICATED (NAI)
- (2) ☐ VOLUNTARY ACTION INDICATED (VAI)
- (3) ☐ OFFICIAL ACTION INDICATED (OAI)
- (4) ☐ NOT AN FDA OBLIGATION
- (5) ☒ REFERRED TO HOME DISTRICT
- (6) ☐ INSUFFICIENT INFO. UNABLE TO EVAL.
- (7) ☐ REFERRED TO OCI

8. FINAL DISPOSITION
- (1) ☒ FOLLOW-UP NEXT E1
- (2) ☐ WARNING LETTER
- (3) ☐ CITATION
- (4) ☐ SEIZURE
- (5) ☐ INJUNCTION / PROSECUTION
- (6) ☐ REFERRED TO OTHER AGENCY (*Indicate Agency in* **Remarks**)
- (7) ☐ RECALL
- (8) ☐ NO ACTION

9. INFO. COPIES TO:
- ☐ HFB-100
- ☐ HFD-730
- ☐ HFV-236
- ☐ HFZ-343
- ☒ HFC-161
- ☒ HFS-636
- ☒ DEN-DO
- ☒ LOS-DO
- ☐ _____
- ☐ _____
- ☐ _____
- ☐ _____
- ☐ _____

REMARKS To: DEN-DO For any required followup at the manufacturer.
To: HFS-636 (Bridgette Wallace).
Det. DO plans no further follow-up.

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NAME AND TITLE OF DISPOSITION OFFICIAL: Michael C. Robinson SE

DISPOSITION: Referred

DISPOSITION DATE: April 27, 1999

FORM FDA 2516a (3/94)

★ U.S. GPO: 1996-404-897/41019

Adverse Event Questionnaire

Complaint Number: DET-0833

Investigator: Anthony R. Petriella

Consumer Information

Date of Report: 3/24/99
MM/DD/YY

Initial Report Source: ☐ORA Consumer Injury

☒Telephone ☐Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted]

Gender: ☐F ☒M

Age: 19

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 1/7/99
Previous Adverse Effects to Product Type:
☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): home

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):

How long did the symptoms last?
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). After taking the product (Metab-X: Metabolic) approx. 2 mos. The consumer experienced sleeplessness, rapid heart rate which later developed into manic / bipolar behavior.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
"Calorad" (dietary supplement), Viagra

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☒No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☒Unknown ☐Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist ☐Other (specify)

What medical tests were performed and what were the results? Blood work: 3/15/99 low platelet count, low lithium level

What was the medical diagnosis? Blood work 2/27/99 high WBC, low lymph's
What treatment(s) was given (e.g., drugs, other)?
Haldol injections Depakote (500mg), Zyprexa (5mg) CBC normal 3/3/99

Were there any preexisting condition(s)/treatment(s)? None
(If YES, list them including allergies, and chronic diseases): ☒Yes ☐No Penicillin

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Complaint/Injury F/U DET-0833
3/24,25,30/99 ARP Att 3a

Product Category

1. Adverse event attributed to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

Other Product Problems

2. ☐Foreign Object
(specify): _____

3. ☐Other (specify):
_____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label): Metaform - Metacut. Dosage 4 capsules 30-6 minutes before workout

Dist/manuf: Metaform
22647 Ventura Blvd #346, Woodland Hills, CA 91346

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☒Check here if ingredients are unknown
(Chromium (as picolinate), Magnesium (as oxide) Potassium (as Citrate) Guarana (Paullinia cupana), Citrimax (Garcinia cambogia) Ma Huang (Ephedra sinica), L Carnitine tartrate, Quercetin

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate categor below:

☐Aspartame
☐Monosodium Glutamate
☐Sulfite
☒Other Ephedrine
☐Unknown

☐Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☒Yes ☐No ☐Unknowr
Product Sample Available: ☒Yes ☐No ☐Unknown

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☐Yes ☑No

Hospitalization: ☒Yes ☐No (if YES, indicate if initial or prolonged) Inpatient hospital stays (in both cases)

Required intervention to prevent permanent impairment/damage: ☒Yes ☐No

Did the adverse event result in a congenital anomaly: ☐Yes ☑No

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date April 2, 1999

From Anthony R. Petriella, Investigator (DET-DO)

Subject Continuation sheet to Complaint/Injury Follow-up – DET-0833

To CFSAN ARMS Monitor Bridgette M. Wallace HFS 636

This was a complaint/injury follow-up investigation conducted in response to a complaint injury report (DET-0833) which generated a CFSAN MedWatch, Project #13370, dated 3/12/99. Complainant believes injuries suffered by sibling were attributed to the ingestion of a food supplement containing Ephedrine. An investigation was performed by DET-DO on 3/24, 25, 30/99. Product samples (C/R #32555) were collected.

Product: Metacuts

Manufacturer: Weider Nutrition International
2002 South 5070 West
Salt Lake City UT, USA 84104
801-975-5000

Distributor: Metaform
22647 Ventura Blvd. #346
Woodland Hills, CA. USA 91346

Complainant: [redacted]

Physicians: [redacted]

SUMMARY OF FINDINGS

The [redacted] residence was visited and interviews were conducted with [redacted] and their mother, [redacted] relating to the events which preceded Mr. [redacted] illness.

Mr [redacted] a white male, D/O/B [redacted] had ingested a total of 47 Metacuts capsules, purchased at a local health food store, between the end of November 1998 and January 27, 1999. In early January 1999 his place of employment, as well as family members, noticed behavioral changes in

Mr [redacted] was later hospitalized for chest pains, insomnia and psychological maladies. All pertinent medical history records were obtained. Attending physicians were interviewed.

Mr [redacted] relinquished custody of the original container and remaining product (10 capsules) to the DET-DO investigator (sample #32555). The investigator provided Mr. [redacted] with a Receipt for Sample (FDA 484) for the item. The product is identified as METACUTS with lot #WN2658A, EXP0901. The product was originally purchased by [redacted] father, [redacted] from:

[redacted]

INTERVIEW WITH COMPLAINANT

On March 24,1999 credentials were shown and a FDA 482 was issued to [redacted] at his place of residence. The complainant, [redacted] was also present. Later that day, [redacted] joined in the interview.

Due to memory lapses occurring in the months of February and March 1999, Mr. [redacted] relayed his recollection of the events beginning in November 1999 with the assistance of his mother and sister. Mr [redacted] signed an affidavit (attached to C/R #32555), dated 3/25/99, describing the events of the previous months.

On or about November 6, 1998, Mr. [redacted] starting taking the Metacuts capsules in hopes of increasing the effectiveness of his work outs at the [redacted] located at [redacted] He continued to take the food supplement - four capsules at a time prior to working out per product directions - until January 27, 1999. On January 7, 1999 his mother noticed that he wasn't getting enough sleep and that he was much more energetic than normal. It was also revealed that on January 26, 1999 his employer observed a change in his behavior in that he wasn't taking directions very well and that he was overly active. On January 28, 1999 Mr. [redacted] was rushed to [redacted] complaining of a windpipe obstruction and chest pains (Exhs. A2/10). After being treated, he was released a couple hours later.

Mr. [redacted] then visited a number of physicians and a therapist/counselor (please refer to affidavit- Att. 6a,6b) on different occasions relating to inadequate sleep, hallucinatory/agitated behavior. Mr [redacted] his sister and his mother stated that he did not have any of the above symptoms prior to taking the Metacuts capsules.

Mr. [redacted] signed a FDA 461, authorizing the release of his medical records. He also signed another medical release form, as required by the [redacted] for release of the [redacted] patient medical records.

INTERVIEW WITH PHYSICIANS

On 3/25/99 [redacted] M.D. was interviewed and his office's records of Mr. [redacted] were collected (Exhs. B 1/16) subsequent to issuance of a signed FDA 461. In addition to Dr. [redacted] records

describing Mr [redacted] initial admission and case summary, some of the records collected at Dr. [redacted] office on 3/25/99 contained other physician's records, notably those of Dr [redacted] Dr. [redacted] stated during the interview that prior to admitting, Mr. [redacted] did not have any previous history of bi-polar behavior and that his change in behavior had a very short onset time. Dr. [redacted] added that the Ma Huang in the food supplement probably triggered the manic-psychotic state. This premise was reinforced in Dr. [redacted] report (Exh. B2) under the heading of Diagnostic Impressions. Please note that the product was referred to as "Megaform" in the patient's report, but the product's correct name is Metacuts. Please also note that, according to [redacted] office manager at Dr [redacted] office, the 2/4/99 changed, handwritten date on the History and Physical Examination (Exh. B1) refers to the date that Dr. [redacted] physically saw Mr. [redacted] not the date of admission, which was 2/3/99. Mr. [redacted] medical records also show that Viagra, as well as a food supplement named "Calorad", was being taken on a daily basis (Exh. B1).

Also on 3/25/99, [redacted] M.D., Mr [redacted] regular physician was interviewed. A signed FDA 461 was also issued and patient records were collected (Exhs. C1,C2) describing Mr. [redacted] visits to Dr. [redacted] from 1/29/99 through 2/15/99. In conversation with Dr. [redacted] Mr [redacted] behavior during examination was very loud, nonsensical and "manicky". Dr. [redacted] stated that Mr [redacted] was a psychologically normal patient in past visits, but he had a complete change in personality. On 3/30/99 additional patient records of care received from Dr. [redacted] prior to 11/17/98 were collected from Dr. [redacted] office (Exhs D1/D11). Also included in the packet of records were laboratory results from [redacted] which revealed elevated albumin, total neutrophils (%), and total neutrophils. Total lymphocytes (%) levels were in the lower than normal range. Drug screening tests were negative (Exhs. D7/D11).

Patient medical records were also collected from the [redacted] (Exhs. E1/E129) on 3/30/99. Mr [redacted] was admitted to the facility psychiatric ward twice: from 2/3/99 to 2/10/99 and from 2/28/99 to 3/7/99 due to psychotic episodes possibly stemming from the use of Metacuts. Please note that the records again erroneously specify "megaform" as the over-the-counter herb ingested (Exh.E21)

As noted in the affidavit, on 2/1/99 Mr. [redacted] visited a psychiatrist, Dr [redacted] as referred by Dr [redacted] Mr [redacted] stated during the interview that he wasn't satisfied with the medical treatment administered by Dr [redacted] and he chose not to revisit him. Dr. [redacted] was not contacted and no patient records were collected.

Also noted in the patient affidavit, on 2/3/99 Mr. [redacted] sought the attention of a licensed therapist/counselor, [redacted] After presenting the signed medical records release form to Mr [redacted] and during his brief interview by the FDA investigator on 3/30/99, it was learned that it was his opinion that Mr. [redacted] needed to be admitted to a psychiatric facility due to Mr [redacted] aggressive and psychotic behavior. No records were collected.

PRODUCT LABELING

The product, Metacuts, is a light-colored grainy substance, individually encapsulated and packaged in a brown glass bottle fitted with a screw cap. The container label is brown, white and gold with white, black gold and red labeling. Intact bottles contain 60 capsules.

ATTACHMENTS

1 a/d CFSAN facsimile: request for follow-up #13370, dated 3/12/99 (pages a/c of facsimile)
d Complaint/Injury report DET-0833, dated 2/22/99
2 a Banyan message announcing CFSAN Project #13370
3 a,b Adverse Reaction Questionnaire DET-0833
4 a FDA 484 Receipt for sample #32555
5 a FDA 461 Authorization for Medical Records Disclosure , signed on 3/24/99
6 a,b Affidavit, signed by [redacted] on 3/25/99
7 a/c Collection report #32555 (w/attachments)

EXHIBITS

A 1 [redacted] release of medical records statement
A 2 Photocopy of [redacted] Authorization to Release Medical Information included in mailing attached to Ambulance E/R records received by FDA
A 3/10 Ambulance/ER records for 1/27/99
B 1/16 Medical records collected from Dr. [redacted] 3/25/99
C 1,2 Medical records collected from Dr. [redacted] on 3/25/99
D 1/11 Medical records collected from Dr. [redacted] on 3/30/99
E 1/130 Medical records collected from [redacted] on 3/30/99
F 1 [redacted] Authorization to Release Medical Information. presented on3/30/99

Anthony R. Petriella
Investigator DET-DO